

### **REMARKS**

Claim 27 has been amended to more particularly point out what Applicants regard as the invention and/or effect minor editorial amendments. Claims 30, 33, 34, and 37 have been amended to recite a proper antecedent basis and/or effect minor editorial amendments. Claim 50, which depends on claim 27 and/or includes all limitations of claim 27, has been added. The amendments are fully supported by the originally filed specification (e.g., page 6, lines 4 to 5; pages 8-9). No new matter has been added.

#### ***Claim Rejection – 35 U.S.C. §112, ¶ 2 (indefiniteness)***

Claims 27, 30, 33, 36-37, 43 and 47-49 stand rejected on the ground that the Markush language of claim 27 is not in a proper form. Applicants disagree. It is well established that a proper Markush language can be written with the phrase "selected from the group consisting of..." Thus, the Markush language of claim 27 is written properly. See MPEP 2173.05(h), para I.

Claims 27, 30, 33, 36-37, 43 and 47-49 stand rejected on the ground that the term "of the culture" of claim 27 makes the claims indefinite. Applicants have changed the term "of the culture" of claim 27 to "of the culture (i)," thereby obviating the rejections.

Claims 27, 30, 33, 36-37, 43 and 47-49 stand rejected on the ground that the terms "isolated" and "removing solid matters" of claim 27 make the claims indefinite. Applicants disagree. The terms are described on, e.g., page 12, lines 17-25 and page 19, lines 3-9 of the originally filed specification. Thus, persons of ordinary skill in the art would understand what the terms mean in light of the specification. *See Energizer Holdings, Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366, 1370-71 (Fed. Cir. 2006) (holding that claims can be held indefinite only where a person of ordinary skill in the art could not determine the bounds of the claims, i.e., the claims were insolubly ambiguous.); *See also* MPEP 2173.02 (providing that when the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims. ... Examiners are encouraged to suggest claim language to

applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.)

Moreover, as the terms are widely used in the art, as disclosed other U.S. patents including, for example, U.S. Patent Nos. 6,534,101; 6,140,077; 5,549,890; and 4,931,398 as well as Sobol et al. (col. 9, lines 9-18), persons skilled in the art would understand what the terms mean. Accordingly, the rejections should be withdrawn.

***Claim Rejections – 35 U.S.C. §102 (anticipation)***

Claims 27 and 30 stand rejected as being anticipated by Perlman ("the Perlman reference"). Applicants traverse for the reasons as set forth below.

Independent claim 27, as amended, recites a feed supplement which comprises at least one of: (i) a culture obtainable by inoculating and cultivating *Lactobacillus gasseri* OLL 2716 (FERM BP-6999) in a medium containing a whey protein derivative; (ii) *Lactobacillus gasseri* OLL 2716 (FERM BP-6999) bodies isolated from the culture (i); and (iii) a supernatant of the culture (i).

For a reference to be anticipatory, (1) it must disclose each and every limitation of the claimed invention, whether it does so explicitly or inherently (see *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed. Cir. 2006); *Scripps Clinic & Research Found. v. Genentech Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991)) and (2) it must also disclose those limitations arranged or combined in the same way as in the claim (see *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1370 (Fed. Cir. 2008)).

The Office has the initial burden of establishing a *prima facie* case of anticipation by pointing out where all of the claim limitations appear in a single reference (see *In re Spada*, 911 F.2d 705, 709 (Fed. Cir. 1990); *In re King*, 801 F.2d 1324 (Fed. Cir. 1986); *In re Angstadt et al.*, 190 USPQ 214 (CCPA 1976)). This failure to address all claimed limitations constitutes a denial of procedural and substantive due process which the Office

is supposed to accord Applicants via the Administrative Procedures Act (see *In re Zurko*, 119 S.Ct. 1816 (1999), *In re Gartside*, 53 USPQ2d 1769 (Fed. Cir. 2000)).

Under the Federal Circuit rules, in order to establish a prima facie case of anticipation relying on the Perlman reference, the Office must show that the Perlman reference teaches at least one of the components (i), (ii), and (iii) recited in claim 27.

Nonetheless, the Office failed to show that the Perlman reference teaches at least one of the components. More particularly, while stating (pages 4 and 5 of the Office Action, a relevant portion of which is reproduced below) that the claimed subject matter and the invention disclosed in the Perlman reference are identical because they both are a feed supplement comprising a supernatant of a culture, the Office identified that such a supernatant of a culture is disclosed in col. 11, lines 25-50 of the Perlman reference.

Claims are drawn to a feed supplement comprising a supernatant of culture.

Perlman teach a feed supplement comprising a supernatant of culture which can be in the form of a dried product and fed to chicks. Note col. 11, lines 25-50.

The claims are identical to the cited disclosure and are, therefore, considered to be anticipated by the teachings of the cited reference.

However, col. 11, lines 25-50, as reproduced below, of the Perlman reference says nothing about such a supernatant of a culture obtainable by cultivating a particular microorganism, *Lactobacillus gasseri* OLL 2716.

The procedure of Example 15 is used with the addition of cobalt nitrate in sufficient quantity to give a concentration of 100 mg. of cobalt per liter of medium instead of the lower level. Examination of the aqueous concentrates by the procedures of Tests 1 to III shows the presence of 5,6-dimethylbenzimidazole-cyanocobalamin. The bioassay of the supernatant liquid is about 1.0 mg. per liter as measured by the *L. leichmannii* bioassay (Test IV).

The cyanocobalamins formed in each of the examples can be converted to the corresponding hydroxocobalamin derivatives by treatment of the former with hydrogen in the presence of platinum oxide in an aqueous medium. The hydroxocobalamins thus formed can then be converted to any desired salt by treatment with the appropriate acid in an aqueous medium.

The vitamin B<sub>12</sub> and other biologically active cobalamins formed in each of the examples can be used in lieu of otherwise-produced vitamin B<sub>12</sub> in promoting growth of chicks. For this purpose, the cobalamin-containing supernate may be merely dried, to provide a cobalamin concentrate; or the cobalamin may be recovered from the supernate or dried concentrate by use of conventional vitamin B<sub>12</sub> purification expedients. The dosage employed (e.g., when added as a supplement to chick feeds) would depend on the potency of the concentrate, or potency of the isolated non-B<sub>12</sub> cobalamin, relative to pure vitamin B<sub>12</sub>.

The invention may be otherwise variously embodied

Therefore, the Office erred in factual findings in rejecting claims 27 and 30 and the rejection should be withdrawn.

### ***Claim Rejections – 35 U.S.C. §103 (obviousness)***

Claims 27, 30, 33, 36-37 and 49 stand rejected as being obvious over the Sobol reference in view of EP 1,112,692 ("the '692 reference"). Claims 43 and 47-48 stand rejected as being obvious over Raczek in view of the Sobol reference and the '692 reference.

The Office stated that (i) the Sobol reference discloses a fermented medium containing *Lactobacillus gasseri* bacterium and teaches that the medium can be used a feed supplement, (ii) although the Sobol reference does not disclose *Lactobacillus gasseri* OLL 2716, the '692 reference teaches that *Lactobacillus gasseri* OLL 2716 has a pharmaceutical efficacy for food products, and (iii) those skilled in the art would thus have substituted the *Lactobacillus gasseri* bacterium taught by the Sobol reference with

*Lactobacillus gasseri* OLL 2716 taught by the '692 reference. It is believed that the Office rejected the claims on the ground that the claimed subject matter is the result of "simple substitution of one known element for another to obtain predictable results" under MPEP 2143B. Applicants traverse for the following reasons.

**A. The Office failed to establish a prima facie case of obviousness.**

Under *KSR* and pursuant to MPEP 2143B, in order to establish a prima facie case of obviousness, the Office must articulate all of the following: (1) a finding that the prior art contained a device (method, product, etc.) which differed from the claimed device by the substitution of some components (step, element, etc.) with other components; (2) a finding that the substituted components and their functions were known in the art; (3) a finding that one of ordinary skill in the art could have substituted one known element for another, and the results of the substitution would have been predictable; and (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Therefore, in order to establish a prima facie case of obviousness relying on the Sobol reference and the '692 reference, the Office must show that: (1) the Sobol reference disclosed a livestock feed supplement which differed from the claimed livestock feed supplement by the substitution of the *Lactobacillus gasseri* bacterium of the Sobol reference with *Lactobacillus gasseri* OLL 2716 taught by the '692 reference; (2) the substituted *Lactobacillus gasseri* OLL 2716 and its functions were known in the art; (3) one of ordinary skill in the art could have substituted the *Lactobacillus gasseri* OLL 2716 for the *Lactobacillus gasseri* bacterium, and the results of the substitution would have been predictable; and (4) whatever additional findings based on the *Graham* factual inquiries

may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

Nevertheless, the Office failed to articulate the findings (2) and (3), among others. More specifically, while stating (pages 6 and 7 of the Office Action, a relevant portion of which is reproduced below) that the '692 reference teaches that *Lactobacillus gasseri* OLL 2716 possesses pharmaceutical efficacy for food products and therefore one of skill in the art would have expected successful results in its use in a feed supplement as claimed in the present invention, the Office failed to identify what pharmaceutical efficacy of *Lactobacillus gasseri* OLL 2716 was known in the '692 reference.

EP '692 teaches *Lactobacillus gasseri* OLL 2716 (FERM BP-6999) useful in a food product, and furthermore that the *L. gasseri* can be pulverized or crushed, note page 9, [0033], lines 34-39.

Claims differ from Sobol in that the specific strain of *L. gasseri* is not disclosed, nor is the crushed form of the *L. gasseri*.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to select for the feed supplement of Sobol et al the specific strain *L. gasseri* OLL 2716 as disclosed by EP '692 because the specific strain is disclosed to possess pharmaceutical efficacy for food products. Therefore, to select for the specific strain, one of skill in the art would have expected successful results for its use in a feed supplement as claimed herein. Each of the claims are taught, or at least suggested, by the cited prior art. In the absence of persuasive evidence to the contrary the claims are deemed *prima facie* obvious over the cited prior art.

Moreover, while stating that the '692 reference teaches that *Lactobacillus gasseri* OLL 2716 is useful in a food product, the Office said nothing about what the word "useful" means with regard to pharmaceutical efficacy of *Lactobacillus gasseri* OLL 2716.

Further, the paragraph [0033], as reproduced below, of the '692 reference does not say anything about pharmaceutical efficacy of *Lactobacillus gasseri* OLL 2716, either.

[0033] The *L. gasseri* strain OLL 2716 was inoculated on 5 liters of MRS liquid culture medium (DIFCO), for stationary culturing at 37 DEG C for 18 hours. After the termination of the culturing, the culture was centrifuged at 7,000 rpm for 15 minutes, to recover a bacterial concentrate of a 1/50 the volume of the liquid culture. Then, the bacterial concentrate was mixed with an equal volume of a dispersion medium containing 10 % (by weight) powdery skim milk and 1 % (by weight) sodium glutamate and was then adjusted to pH 7, and the resulting mixture was subsequently freeze-dried. The resulting freeze-dried product was pulverized with a sieve of 60 mesh, to recover a freeze-dried bacterial powder.

As discussed above, since the Office failed to show that the functions – pharmaceutical efficacy – of *Lactobacillus gasseri* OLL 2716 were known in the art, it cannot be concluded that one of ordinary skill in the art could have substituted *Lactobacillus gasseri* OLL 2716 disclosed in the '692 reference for *Lactobacillus gasseri* bacterium known disclosed in the Sobol reference and the results of the substitution would have been predictable.

Accordingly, the Office failed to establish a prima facie case of obviousness.

**B. The results of substitution of *Lactobacillus gasseri* OLL 2716 of the '692 reference for *Lactobacillus gasseri* bacterium of the Sobol reference would not have been predictable.**

In the present invention, the function of *Lactobacillus gasseri* OLL 2716, when it is administered to a livestock, is to enhance intestinal flora-improving activity, antidiarrhea activity, antioxidant activity, weight-increasing activity, and growth-promoting activity of the livestock. By contrast, the '692 reference describes that the function of *Lactobacillus*

*gasseri* OLL 2716, when it is administered to a human patient, is to disinfect *Helicobacter pylori* in the human stomach.

More specifically, prior to the invention of the '692 reference, antibiotics were administered to a human patient to disinfect *Helicobacter pylori* in its stomach. The problems associated with the administration of the antibiotics were occurrence of antibiotic-resistant *Helicobacter pylori* and occurrence of severe side effects (see paragraph [0003] of the '692 reference). The inventors of the '692 reference discovered that *Lactobacillus gasseri* OLL 2716 showed an unexpectedly superior effect of disinfecting *Helicobacter pylori* in a human stomach without causing the problems associated with the antibiotics. (see paragraphs [0004] and [0010] of the '692 reference; and paragraph [0041] of the '692 reference.)

In accordance with the invention, the disinfection of *H. pylori* and/or the protection against infection with *H. pylori* can be practiced efficiently with no occurrence of side effects. The composition of the invention is absolutely not problematic in terms of safety profile and can be freely prepared in the forms of dairy products and other various food or drink products, so the composition can be ingested by healthy people as well as babies and infants, aged people, valetudinarians, and convalescents and the like for a long period of time and exerts a particularly excellent prophylactic and/or therapeutic effect of gastritis, gastric ulcer and the like. (paragraph [0041] of the '692 reference; underlines added for emphasis.)

As shown above, the '692 reference clearly and unambiguously describes that *Lactobacillus gasseri* OLL 2716 has the effect of disinfecting *Helicobacter pylori* in a human stomach. Nothing in the '692 reference suggests the applicability to a livestock and the resulting effects of enhancing intestinal flora-improving activity, anti-diarrhea activity, antioxidant activity, weight-increasing activity, and growth-promoting activity of the livestock.



Accordingly, the results of substitution of *Lactobacillus gasseri* OLL 2716 of the '692 reference for *Lactobacillus gasseri* bacterium of the Sobol reference would not have been predictable.

**C. The Office's conclusion of obviousness was based on impermissible hindsight reasoning.**

In making a 35 U.S.C. 103 rejection, the Office has the initial duty of supplying the requisite factual basis and may not, because of doubts that the invention is patentable, resort to speculation, unfounded assumptions or **hindsight reconstruction** to supply deficiencies in the factual basis." *In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967) In order not to be impermissible hindsight reasoning, Office's judgment must take into account **only** knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and **must not include** knowledge gleaned only from applicant's disclosure." *In re McLaughlin* 443 F.2d 1392, 1395 (CCPA 1971).

In rejecting claims 27, 30, 33, 36-37 and 49 of the instant application, the Office extrapolated *Lactobacillus gasseri* OLL 2716 to the effects of enhancing intestinal flora-improving activity, antidiarrhea activity, antioxidant activity, weight-increasing activity, and growth-promoting activity of a livestock. However, as discussed above, such effects resulting from *Lactobacillus gasseri* OLL 2716 were not within the level of ordinary skill in the art at the time of the claimed invention. Rather, the Office's extrapolation includes knowledge gleaned only from the instant application.

Therefore, the Office relied on impermissible hindsight reasoning.

**D. Selecting *Lactobacillus gasseri* OLL 2716 from an infinite number of choices is not obvious.**

Under *KSR*, a claimed invention is obvious if it was chosen from a finite number of identified, predictable solutions, with a reasonable expectation of success.

In the instant application, there were virtually an unlimited number of *Lactobacillus gasseri* bacteria available. Each of these unlimited number of *Lactobacillus gasseri* bacteria has its own unique characteristic. None of the prior art teaches that *Lactobacillus gasseri* OLL 2716, which was known to reduce the number of *Helicobacter pylori* in human stomach, would also have had the effects of enhancing intestinal flora-improving activity, antidiarrhea activity, antioxidant activity, weight-increasing activity, and growth-promoting activity of a livestock. Thus, it would not have been obvious for one of ordinary skill in the art to select *Lactobacillus gasseri* OLL 2716 from an infinite number of choices with a reasonable expectation of success.

For at least foregoing reasons, the obviousness rejections should be withdrawn.

Accordingly, this application is in condition for allowance.

A two-month time extension is requested. However, the Director is hereby authorized and requested to charge any deficiency in fees.

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Respectfully submitted,

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